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What does BRIDG stand for?

BRIDG stands for **B**iomedical **R**esearch **I**ntegrated **D**omain **G**roup. However, the primary value of the acronym is the word “BRIDG”, which represents a bridge between organizations, technical and domain experts, and different clinical information models.

What is the BRIDG project?

The BRIDG Project is a collaborative effort engaging stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Work Group (RCRIM WG), the National Cancer Institute (NCI) and its Cancer Biomedical Informatics Grid (caBIG®), and the United States Food and Drug Administration (FDA). The goal of the BRIDG Project is to develop a shared view of the data, relationships, and processes which collectively define the domain of “protocol-driven research and its associated regulatory artifacts.” Specifically, the formal definition of the domain-of-interest for the BRIDG Project stakeholders is:

- Protocol-driven research and its associated regulatory artifacts, i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, subject characteristic, biologic, cosmetic, food or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

A shared view of the various data structures and processes that define the BRIDG Model’s domain-of-interest is essential in achieving the larger goal of semantic interoperability (SI) both among people (human semantic interoperability (HSI)) and systems (computable semantic interoperability (CSI)). Through the explicit definitions of shared semantics, either HSI or CSI (depending on the desired goal in a particular context) is possible both *within* the BRIDG domain-of-interest and *between* the BRIDG domain and other ‘intersecting’ domains (e.g. Public Health, healthcare, etc.).

In particular, the goal of defining and representing the shared semantics (aka “meaning”) of the BRIDG Model’s domain-of-interest means that the primary focus of the BRIDG Project is the gathering and documenting of the various business processes (dynamic semantics), data structures (static semantics), and relationships (static and dynamic semantics) that collectively are required to support HSI and/or CSI.

The BRIDG Project produces the requisite view of shared semantics as an object-oriented class model expressed in the Unified Modeling Language (UML) and as an HL7 model based on the HL7 Reference Information Model (RIM). The class model documents classes, attributes, constraints, assumptions, examples and relationships between classes. Several class diagrams are provided, including a comprehensive diagram and five smaller

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diagrams representing various areas within the model. The class model is supplemented by state transition models and instance models. Collectively, these models and their diagrams form the BRIDG Model. The RIM-based model represents the same semantics as the UML-based model, but expresses them using the classes and structural vocabulary provided by the HL7 RIM. The RIM-based model also includes mappings to the UML classes and attributes. It consists of a single primary diagram as well as a number of smaller supplemental diagrams representing re-usable constructs referenced by the primary diagram.

Although the BRIDG Model itself is the primary artifact that is being incrementally assembled by the BRIDG Project, there are several additional artifacts of interest, e.g. project mapping documents and users guide, which describe in some detail various aspects of how a specific project team utilizes/can utilize the BRIDG Model in its efforts to build message structures and/or applications that support SI at either the HSI or CSI level (the latter, of course, being at least an order-of-magnitude more difficult than the former). Details of these various artifacts are available within the current Documentation Package or at www.bridgmodel.org.

Where do I find the BRIDG Model?

BRIDG Model www.bridgmodel.org
BRIDG GForge Project Page <http://gforge.nci.nih.gov/projects/bridg-model/>
BRIDG GForge File Release Site http://gforge.nci.nih.gov/frs/?group_id=342

Why was BRIDG created? What is a Domain Analysis Model (DAM)? What is BRIDG used for? What is its purpose?

The goal of the BRIDG Project is to produce a *shared view of the dynamic and static semantics* of a common domain-of-interest, specifically the domain of *protocol-driven research and its associated regulatory artifacts*.

For BRIDG, this shared view is captured as a Domain Analysis Model (DAM). A DAM is a conceptual representation of an area of interest. It is used for conveying an understanding of the domain and allowing that understanding to be assessed by others to aid in reconciling multiple perspectives of the domain.

A shared semantic view is essential if the clinical research community – both in-and-of-itself and as part of the larger healthcare and life sciences communities – is to achieve computable semantic interoperability (CSI), i.e. the ability for information systems to exchange at a machine-to-machine level the meaning (rather than simply the structure) of data and/or to effectively combine functionality across machine/system boundaries. Stated another way, in order to realize the various data interchange and application interactions that are known by members of the BRIDG stakeholder organizations to be requirements for CSI, a shared view of dynamic and static semantics must be established.



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Through the efforts of the BRIDG Project, this shared view or DAM is expressed as a collection of visual diagrams which are, in turn, expressed using the iconography and grammar of both the Unified Modeling Language (UML) and the HL7 Reference Information Model (RIM). This set of visual diagrams plus the underlying inter-diagram relationships, definitions, explanations, and examples are collectively referred to as the BRIDG Model.

Who is the intended audience (user) of BRIDG?

The target audience for the BRIDG Documentation Package is, first and foremost, anyone with an interest in learning more about the BRIDG Project in general, and specifically about the current release of the BRIDG Model. In particular, the BRIDG Semantic Coordination Committee (SCC) – the authors of this document – expects that the content of the Documentation Package will be of use to:

- domain experts working within the domain scoped by the BRIDG Model
- analysts, architects, and developers working on defining specific data interchange semantics (e.g., message specifications) or application APIs
- terminologists / ontologists interested in augmenting current work involving building ontologies in the BRIDG Model domain-of-interest.

Who sanctions/certifies BRIDG? How? How are decisions made and documented relative to BRIDG? Who is the owner of BRIDG? How are they organized?

The BRIDG Project is a collaborative effort engaging stakeholders from four organizations:

- Clinical Data Interchange Standards Consortium (CDISC)
- HL7 Regulated Clinical Research Information Management Work Group (RCRIM WG)
- National Cancer Institute (NCI), including the Cancer Biomedical Informatics Grid (caBIG[®]) project
- United States Food and Drug Administration (FDA)

The term “BRIDG Model” (or simply “BRIDG”) is used to refer to the Unified Modeling Language (UML) and HL7 RIM-based models whose semantics are collectively defined by its various contributors, as well as to the organizational governance and model management, maintenance, and evolution processes defined and executed by various members of the four BRIDG stakeholder organizations. From a governance perspective, there are two groups that operate in the overarching context of the BRIDG Project to oversee the ongoing management, maintenance, support, and evolution of the BRIDG Model: the BRIDG Board of Directors (BoD), and the Semantic Coordination



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Committee (SCC). Following is a brief description of each group's organization and responsibilities in the context of the overall BRIDG Project.

The BRIDG Board of Directors (BoD)

As mentioned above, the scope, content, organization, and processes of the BRIDG Project are currently defined and supported by four stakeholder organizations: HL7 RCRIM WG, NCI and NCI caBIG[®], CDISC, and FDA. The BoD was established to provide the four stakeholder organizations with a semi-formal mechanism to direct and monitor the content, management, maintenance, support, and evolution of the BRIDG Model. The BoD meets monthly and is charged with the general governance of the BRIDG Project, including the prioritization and scheduling of content submitted to the SCC for inclusion in the BRIDG Model. In establishing priorities and schedules for harmonization of specific content, the BoD strives to maintain an overall balance of perspective in the BRIDG Model, ideally allowing no single stakeholder organization or project perspective to dominate the harmonization schedule – and therefore the BRIDG Model's content – to the exclusion of the others. Operationally, harmonization priority decisions are made based on consideration of a number of factors including stakeholder balance, overall semantic content balance of the BRIDG Model, state of the project's "harmonizable artifacts" (see below), and an overview of the entire project execution space to make sure complimentary or possibly redundant project content is scheduled concurrently or sequentially whenever possible. The BoD is composed of 4 appointed members, one from each of the 4 stakeholders, and currently 5 elected members who are nominated by the stakeholder communities and voted on by the board members. The current board members can be found at: <http://www.bridgmodel.org/directors>.

The Semantic Coordination Committee (SCC)

Although the BRIDG BoD defines the overall prioritization and scheduling decisions as to which content will be moved into the BRIDG Model when, the actual process of representing the semantic content from a given project in the BRIDG Model is the responsibility of the SCC. This includes making the decisions regarding how a given project's static or dynamic content are *represented* in the BRIDG Model as a whole.

Each project brings to a scheduled SCC meeting its harmonizable artifacts. These include:

- UML class and instance diagrams documenting the project's static content (as well as a Mapping Document which lists the project team's working assumptions as to how the project's static semantics can be mapped to the current BRIDG Model static content),
- UML state diagrams and other artifacts documenting the project's dynamic content, and
- A list of well-defined concepts, attributes, and/or relationships which are present in the project but absent in the current version of the BRIDG Model. (i.e., static

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semantics that the project team has been unable to map to existing BRIDG static structures and which are thus not part of the project team's Mapping Document).

The project's collective (static) content, i.e. the sum of the static harmonization artifacts enumerated above, is then analyzed by the SCC in continuous dialogue with project team members to arrive at a consensus and shared understanding of the chosen representation of the project team's semantics in the BRIDG Model. The process is collectively referred to as 'harmonization.' Interested readers can refer to a more detailed discussion of the harmonization process in chapter 3 of the User's Guide that accompanies each release of the BRIDG Model. It is available at http://gforge.nci.nih.gov/frs/?group_id=342

The SCC also has the ongoing responsibility of ensuring that the semantics that are represented in the BRIDG Model are expressed formally via the HL7 Reference Information Model (RIM). This commitment is part of the overarching commitment to ensure that CDISC and HL7 implementations of BRIDG semantics are, in fact, interoperable. It also acts as a quality assurance step on the representation of BRIDG semantics.

For more details about the SCC, please refer to Section 3.2 of the User's Guide that accompanies each release of the BRIDG Model. It is available at http://gforge.nci.nih.gov/frs/?group_id=342

Who created the BRIDG Model? When was BRIDG created? What is the history of the BRIDG project?

The idea that became BRIDG started with the 2003 Clinical Data Interchange Standards Consortium (CDISC) effort to harmonize CDISC standards with HL7 and also internally within CDISC. Based on the recommendation from an assessment of the current CDISC and HL7 standards environment, the CDISC Board of Directors funded an effort to build a CDISC Domain Analysis model, which was delivered in early 2005.

In early 2004, the National Cancer Institute (NCI) began a project to develop a structured model of a clinical trial protocol as part of the Cancer Biomedical Informatics Grid (caBIG[®]) project. After recognizing the benefits of collaborating with CDISC and HL7 Regulated Clinical Research Information Model (RCRIM) on a shared model, the NCI Cancer Structured Protocol Representation (caSPR) team was included in the domain analysis modeling effort.

An early version of the BRIDG Model was presented to the HL7 RCRIM work group in late-2005/early-2006 and was subsequently accepted as the single Domain Analysis Model (DAM) for use by HL7 RCRIM in support of their compliance with the HL7 Development Framework (HDF) and its increased focus on robust representation of implementation-independent requirements. The US Food and Drug Administration (FDA) became involved as a stakeholder through RCRIM.

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The first formal release of BRIDG was published in June 2007. Subsequent releases have occurred approximately twice a year since then.

For more details about the history of BRIDG, please refer to Section 3.1 of the User's Guide that accompanies each release of the BRIDG Model. It is available at http://gforge.nci.nih.gov/frs/?group_id=342

How often is BRIDG updated?

There is a new release of the BRIDG Model once or twice a year at the discretion of the BRIDG SCC based on harmonization schedules. Documentation for the BRIDG Model is also updated with each release and details of the changes from one release to the next are covered in the Release Notes.

How is BRIDG updated? What is harmonization?

The BRIDG Model is updated via a process known as harmonization. Harmonization is the process whereby multiple perspectives on a given problem are presented to an informed, neutral group who must decide if the various perspectives represent the same or different semantic content. Harmonization is focused on distinguishing true differences in meaning from differences of representation. Any project team working in a domain whose semantics are within or partially overlap with the semantics defined by the BRIDG Model can influence updates to the BRIDG Model through harmonization. The only requirement for participating in this process is the preparation by the interested team of BRIDG harmonizable artifacts. These artifacts include the set of class, instance, activity, state, and/or sequence diagrams that define the project team's specific semantics. The project team and the Semantic Coordination Committee (SCC) collectively harmonize the artifacts into the larger BRIDG Model. In addition, each team should provide a mapping spreadsheet that maps each item in the project model to the most current BRIDG release to the best of their ability.

Project teams wishing to harmonize their content with BRIDG or to discuss the logistics of BRIDG harmonization are urged to contact the members of the BRIDG SCC. SCC members can be reached either directly (email addresses can be found at <http://www.bridgmodel.org/htc>) or through the SCC listserv (bridgTHC-L@list.nih.gov).

Another way to influence updates to the BRIDG on a smaller scale is to post enhancement requests on the BRIDG's GForge site. BRIDG's GForge Tracker can be found at https://gforge.nci.nih.gov/tracker/?group_id=342.



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How does the BRIDG Model relate to similar efforts? What is the advantage of BRIDG?

As a Domain Analysis Model (DAM), BRIDG is intended to cover the domain of protocol-driven research and associated artifacts. This domain naturally overlaps with numerous other domains, some of which have domain analysis models already in process while others do not. For example, the NCI's Life Sciences Domain Analysis Model (LSDAM) overlaps with BRIDG in some areas while having a substantially different scope. The LSDAM was developed by mapping common concepts to BRIDG and extending them or adding new associations that represent concepts from the life sciences. HL7 has several models whose semantics overlap with BRIDG, such as the Clinical Statement (which does not have a DAM at this time), the Individual Case Safety Report (ICSR) message (which has a DAM in process), and others. As the BRIDG team becomes aware of other DAMs and those DAMs become mature models, the BRIDG Semantic Coordination Committee (SCC) hopes to harmonize with those projects the common semantics. After such a harmonization effort, it is possible that the sub-domains in BRIDG may shrink or give way to references to other DAMs which more reasonably are the "home" model of those semantics of which the BRIDG Model will make use. BRIDG may also end up expanding if the need arises to cover other areas brought by new projects whose semantics are not yet harmonized into the model.

From another perspective, the BRIDG Model may be the basis for deriving various levels of project implementation models with obvious additions or changes to accommodate implementation-specific requirements.

The key advantage of the BRIDG Model is that it is a shared view of the semantics of protocol-driven research as understood by the four major stakeholders and as such represents countless hours of consensus development. Clinical Data Interchange Standards Consortium (CDISC) heavily relies upon the BRIDG Model in its efforts to create an integrated set of standards; NCI is building services with the static semantics based on BRIDG; HL7 Regulated Clinical Research Information Management (RCRIM) has endorsed BRIDG as its DAM and is considering a BRIDG-based model as its candidate Domain Message Information Model (DMIM); and BRIDG is on its way to becoming an International Organization for Standardization (ISO) standard. With the reliance on BRIDG, each of these organizations is able to achieve increased computable semantic interoperability.

Why should I use BRIDG? Why should I get involved? Why should I care?

It is important to note that the overarching, primary use case for the BRIDG Model is the need to achieve computable semantic interoperability (CSI) both *within* the domain of protocol-driven research as well as *between* this domain and others that may intersect with it at the interoperability level. For example, the domains of protocol-driven research and public health both share the concept of adverse events. It is beyond the scope of this BRIDG FAQ to discuss the full details of CSI, but a summary of the so-called *Pillars of Computable Semantic Interoperability* can be stated as follows:



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- **Pillar #1:** Common model across the domains/sub-domains-of-interest
- **Pillar #2:** Computationally robust data type specification
- **Pillar #3:** Framework for binding context-specific terminologies to model elements
- **Pillar #4:** Methodology for constructing interoperability “building blocks” (e.g. data interchange structures or application service specifications) that are built around successful construction of Pillars #1 - #3

The BRIDG Model is a manifestation of Pillar #1. The BRIDG Model supports Pillar #2 through the specification of each BRIDG Model attribute using the ISO 21090 data type standard. Pillar #3 is currently being addressed within the NCI through the binding of attribute-specific value sets and their management in Cancer Data Standards Repository (caDSR) and Enterprise Vocabulary Services (EVS). A critical component of Pillar #3 if one is to move from the state of the pillar being ‘necessary but not sufficient’ is that the terminologies which comprise the various attribute-bound value sets be managed under a formal terminology management process that deals with the problems of *intra-terminology version management* and *inter-terminology equivalence (or other semantic relationships)*. Not all organizations will address Pillar #4 in the same way. However, the NCI is addressing Pillar #4 as it adopts the approach commonly known as Services-Aware Interoperability Framework (SAIF) and especially the Enterprise Conformance and Compliance Framework (ECCF) (description of these frameworks is outside the scope of this document).

What information or components are in the BRIDG Model?

There are four ways to interpret this question:

- What concepts are included in the BRIDG Model?
- What are the components of the BRIDG Model as a UML-based Domain Analysis Model (DAM)?
- What components of the BRIDG Model are developed for the target audiences of the model?
- What components are in a BRIDG release package?

What concepts are included in the BRIDG Model?

The BRIDG concepts are represented by classes that are grouped into sub-domains packages in the Enterprise Architect (EA) file. The sub-domains logically group related classes and include the following:

- Common sub-domain: people, organizations, various roles, products, places



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- Protocol Representation sub-domain: protocol document and amendments, study design, study agents and arms, planned study personnel, sites and resources
 - Study Conduct sub-domain: scheduled and performed activities, results, actual study personnel, sites and resources, study status
 - Adverse Event sub-domain: adverse events, actions taken, causality, seriousness, outcome, product investigation
 - Regulatory sub-domain: regulatory applications, submissions, sponsors, assessments

All classes have associations to other classes within and/or across sub-domains.

What are the Components of the BRIDG Model as a UML-based Domain Analysis Model (DAM)?

A domain analysis model (DAM) has two major types of components: static and dynamic. The static components include the class diagrams and instance diagrams which describe the concepts, attributes, and relationships of the domain-of-interest. The dynamic components include the storyboards, activity diagrams, state diagrams, sequence diagrams, etc. that define the various processes and dynamic behavior of the domain. The BRIDG Model is primarily composed of static components, but does contain some dynamic components, primarily state transition diagrams.

What components of the BRIDG Model are developed for the target audiences of the model?

The BRIDG Model uses a multi-perspective approach to modeling the static semantics of protocol-driven research. Each perspective tailors the representation of the semantics to a different audience. The current 3 perspectives are represented in the following diagram:

Perspectives of BRIDG

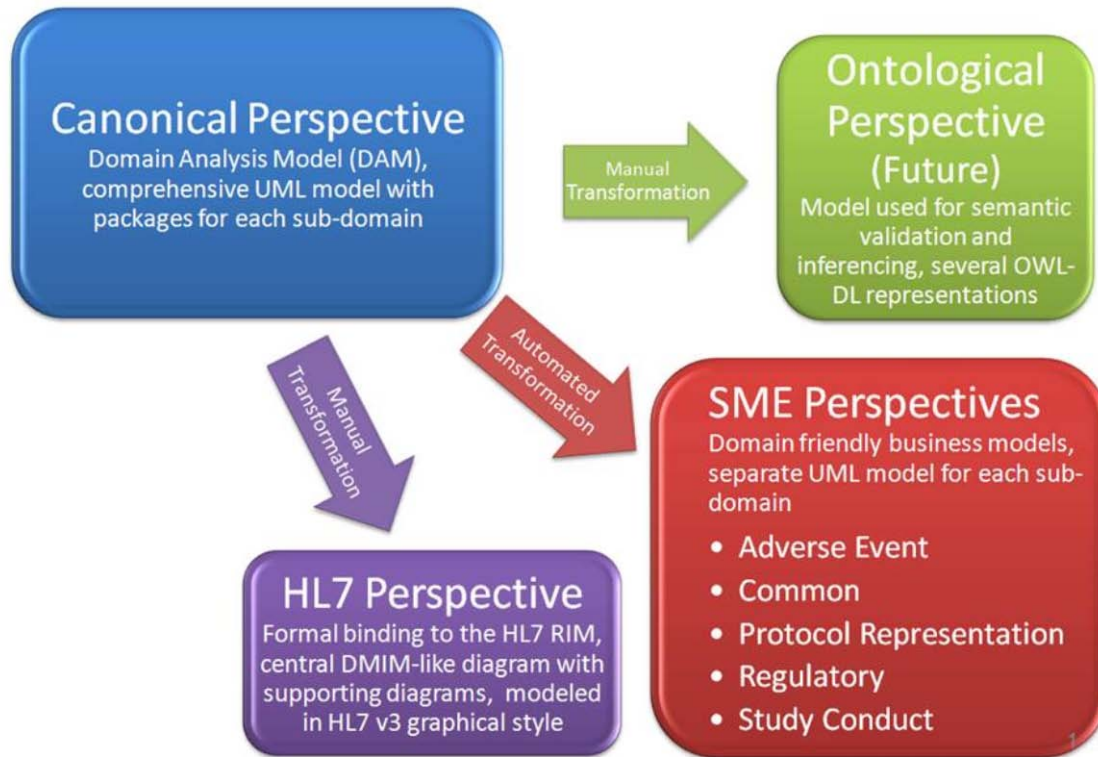


Figure 1 Perspectives of BRIDG

The Subject Matter Expert (SME) Perspective is designed to be used by domain and subject matter experts. It presents the semantics in a domain friendly way, grouping related classes into 5 Unified Modeling Language (UML) models that cover the spectrum of the comprehensive model, but narrow the scope of each class diagram to a subset, or sub-domain of the BRIDG Model. Transformers are used to automatically generate the SME Perspective from the Canonical Perspective. The Canonical Perspective is designed for information analysts and application developers. It presents the comprehensive model in a single UML class diagram that shows the full context of every class in relation to the whole. Classes are still collected in sub-domain-based packages, but all are present in a single Enterprise Architect (EA) file. The HL7 Perspective is designed to be used by HL7-savvy users. It presents the same semantics as in the UML model but using HL7 Reference Information Model (RIM) classes grouped into a primary Domain Message Information Model (DMIM) diagram and a number of supporting diagrams. The HL7 Perspective is created by manually mapping the UML semantics to the RIM classes and attributes. Future releases of BRIDG may also contain an Ontological perspective of the comprehensive set of semantics, but it is uncertain at this time when this will be included.



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The dynamic semantics of the BRIDG Model are presented in a number of instance diagrams, state diagrams, etc. using the UML. The vast majority of semantics that have been harmonized into BRIDG are static so the dynamic semantics are a smaller set of the whole. However, the NCI has documented many of the dynamic semantics of protocol-driven research in its Biomedical Research Business Architecture Model (BAM) and the BRIDG Semantic Coordination Committee (SCC) refers readers to that project to supplement content provided directly in the BRIDG Model. For more information on the BAM, see the following site: <https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/BAM>.

For a more detailed discussion of the BRIDG Model components, please refer to Section 4 of the User's Guide that accompanies each release of the BRIDG Model. It is available at http://gforge.nci.nih.gov/frs/?group_id=342

What components are in a BRIDG release package?

A BRIDG Model release package contains, at a minimum, the following items:

- UML-Based Models
- RIM-Based Models
- Report of Comprehensive UML-Based Model
- XMI of Comprehensive UML-Based Model
- Release Notes
- User's Guide
- BRIDG Domain Analysis Static Model Style Guide
- BRIDG Change List
- BRIDG Mapping Spreadsheet

For a complete list of package contents, see section 5.10 of the BRIDG User's Guide.

How do I read the BRIDG Model? What is UML? How do I navigate the model?

This question can be interpreted in several ways:

- How do I read a UML model?
- How do I read an HL7 model?
- How do I navigate the BRIDG Enterprise Architect file?

How do I read a UML Model?

The purpose of this FAQ is not to explain the details of Unified Modeling Language (UML); however a few brief comments are in order. The UML is a "standardized general-purpose modeling language in the field of software engineering" and is defined by an organization called the Object Management Group (more information available at <http://www.omg.org/>, quoted text is referenced from



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http://en.wikipedia.org/wiki/Unified_Modeling_Language). While UML might not be easy to understand for all domain experts, the BRIDG SCC has found that most domain experts can become comfortable with it or at least work with an analyst who assists in interpreting the model to help ensure needed semantics are in the model. Additionally, the BRIDG SCC has made representation decisions that occasionally diverge from the most strict interpretations of UML for the sake of accessibility to non-technical readers, such as using class-level constraints as visual clues or reminders of business rules binding how classes and/or attributes can be used.

How do I read an HL7 Model?

HL7 provides a good summary document explaining how to interpret HL7 diagrams and how to understand core HL7 modeling constructs. It is called the “V3 Guide” and can be found here: <http://www.hl7.org/v3ballot/html/help/v3guide/v3guide.htm>.

How do I navigate the BRIDG Enterprise Architect file?

The Project Browser enables you to navigate through the Enterprise Architect project (EAP) space. The BRIDG Model EAP contains five high-level packages, each containing diagrams, elements, and element properties. Below is the high level package structure:

1. **BRIDG – Start Here:** a brief overview;
2. **BRIDG Domain Analysis Model:** a set of two high-level diagrams and five (5) sub-packages that dissect the BRIDG Model into management chunks of relevant content in sub-domain areas of interest to BRIDG users:
 - a. **BRIDG Sub-Domain Package Diagram:** a high-level diagram showing a package view of each of the five (5) BRIDG sub-domains and the classes in each package;
 - b. **UML-Based Comprehensive BRIDG Model Diagram:** a high-level diagram showing the complete BRIDG Model and specifically, for each class where it's applicable, the complete set of attributes for the class, partitioning the attributes as to whether they are “local” to the class or inherited from the class's super-type hierarchy;
 - c. **Adverse Event Sub-Domain:** the set of classes related to adverse events, causality assessments, etc., and a diagram showing associations between these classes and other areas of the overall model;
 - d. **Common Sub-Domain:** the set of classes that are used by two or more other sub-domains and a diagram that shows the associations between them that are also commonly used;
 - e. **Protocol Representation Sub-Domain:** the set of classes that define a study protocol, the activities that are part of the study plan and a diagram showing the associations among them;
 - f. **Study Conduct Sub-Domain:** the set of classes dealing with the scheduling, execution and results of study activities for study subjects,



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study sites and study administration, and a diagram showing their associations;

3. **BRIDG State Transition Diagrams:** a set of DRAFT state transition diagrams illustrating values and workflows of statusCode attributes used throughout the BRIDG Model;
4. **BRIDG Instance Diagrams:** a set of instance diagrams that explore real world examples using BRIDG static elements and the associations between the, including adverse event reporting, a few domains from CDISC's Study Data Tabulation Model (SDTM), the organizational structure of a cooperative group, and a sampling of typical trials designs;
5. **ISO 21090 Data Types:** a set of packages, classes, attributes, flavors, constraints, enumerations, etc that collectively define the data type specification for ISO 21090, a Draft International Standard in the ISO process.

What tools do I need to view the BRIDG Model?

The Unified Modeling Language (UML) representation of the BRIDG Model is maintained in Enterprise Architect Project (EAP) from Sparx Systems. A free viewer which enables full traversal and inspection of the complete BRIDG Model (which is an .EAP file) can be downloaded from the Sparx Systems website (<http://www.sparxsystems.com.au/>). Alternatively, included in the BRIDG release package are an RTF report of the BRIDG EAP file which can be viewed using a word processor and an XMI export of the BRIDG EAP file which can be imported into most UML modeling tools.

The HL7 artifacts are published in three different views – JPGs of the Visio diagrams, HTML table views and Excel spreadsheet views of the model content. To view the JPG HL7 artifacts, all that is needed is a JPG viewer. To see the HTML table view, a web browser is needed. To view the Excel spreadsheet views, either a copy of Excel or the free Microsoft Excel Viewer is needed.

All supporting documentation is published in Microsoft Word.

Is there a glossary or dictionary for the BRIDG Model?

Yes, for a BRIDG Model glossary, please refer to Section 6 of the User's Guide that accompanies each release of the BRIDG Model. It is available at http://gforge.nci.nih.gov/frs/?group_id=342.

In addition, definitions for all classes, attributes, and associations can be found in the BRIDG Model. For information on how to read the BRIDG Model, see the related question above.

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Who do I contact with questions or comments about BRIDG?

Questions or comments about the BRIDG Model can be directed to one of the members of the Semantic Coordination Committee (SCC) either directly (email addresses can be found at <http://www.bridgmodel.org/htc>) or through the SCC listserv (bridgTHC-L@list.nih.gov). Questions can also be posted to the BRIDG Users listserv (BRIDG_USERS@list.nih.gov).

Questions about BRIDG strategy and direction can be directed to the BRIDG SCC or BRIDG Users listservs and will be forwarded to the BRIDG Board of Directors (BoD).

Alternatively, comments, issues and requests can be submitted through the BRIDG GForge Tracker utility located at: https://gforge.nci.nih.gov/tracker/?group_id=342.

How can I influence the BRIDG Model? How do I get involved?

Project teams wishing to harmonize their content with BRIDG or to discuss the logistics of BRIDG harmonization are urged to contact the members of the BRIDG SCC. SCC members can be reached either directly (email addresses can be found at <http://www.bridgmodel.org/htc>) or through the SCC listserv (bridgTHC-L@list.nih.gov).

Who is using BRIDG? How?

A number of organizations are using the BRIDG Model for both application development and message specification. In particular, the HL7 Regulated Clinical Information Management (RCRIM) Work Group specifies that the BRIDG Model is to be used as the starting point, i.e. the Domain Analysis Model (DAM), for all RCRIM message specifications.

Clinical Data Interchange Standards Consortium (CDISC) is using BRIDG as the basis of their analysis models and led the effort to make BRIDG an International Organization for Standardization (ISO) standard (passed initial ballots in May). CDISC is also using BRIDG as the underlying domain model for the Shared Health And Research Electronic Library (SHARE) project.

The National Cancer Institute's caBIG[®] program has standardized on the BRIDG Model for all applications developed within the Clinical Trial Management System (CTMS) Work Space. In particular, this means that: a) all classes and attributes in the static BRIDG Model are registered in the Cancer Data Standards Repository (caDSR) / Enterprise Vocabulary Services (EVS) semantic infrastructure that forms the semantic backbone of the Clinical Trials Management Systems (CTMS); and b) all applications and services must build their analysis models based on the BRIDG Model. Additionally, the National Cancer Institute (NCI) used common semantics from BRIDG when building its Life Sciences Domain Analysis Model (LSDAM). The Clinical Trials Registry



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Program (CTRP) at the NCI also used a BRIDG-based model underlying the application. The NCI's standardized case report forms (CRFs) are also being harmonized with the BRIDG Model.

The United States Food and Drug Administration (FDA) has harmonized the Individual Case Safety Report (ICSR) semantics with BRIDG.

Outside of the stakeholder organizations, the Federal Health Information Management Systems project (FHIMS) is using the BRIDG Model to harmonize their core concepts for the National Health Information Network (NHIN) effort. Pharmaceutical companies are beginning to build BRIDG-based applications and repositories. Software vendors in the healthcare arena are leveraging BRIDG semantics in the development of their core products.

How much does BRIDG cost?

There is no charge for accessing or using any of the BRIDG content. It should be noted, however, that each attribute in the BRIDG static model is bound to one and only one data type as specified by the International Organization for Standardization (ISO) data type specification 21090. As such, if an organization chooses to build an implementation of some or all of the semantics specified in the BRIDG Model, the organization must support an implementation of the required data types. However, since ISO 21090 is not yet a fully-balloted standard, there are no restrictions on use of these pre-ballot materials.

What are the current activities in BRIDG?

The BRIDG Semantic Coordination Committee (SCC) publishes a planned schedule of upcoming harmonization activities on its web site at <http://bridgmodel.org> under the section entitled Current Activities and Harmonization Plan.

What versions of BRIDG are supported?

New releases of BRIDG are produced once or twice a year. The current release and all historical releases of BRIDG can be found on the BRIDG website at <http://bridgmodel.org>. Once released, prior versions of BRIDG are not maintained. New features and the results of mapping new projects or new versions of existing projects are reflected only in the newest release of BRIDG after the mapping is completed. The BRIDG Semantic Coordination Committee (SCC) is presently discussing mechanisms to aid implementers which must integrate applications based on different versions of BRIDG to map between the different release expressions. Organizations adopting the BRIDG Model are expected to manage any software or infrastructure that is dependent on a particular version of BRIDG in the same fashion that they would manage dependencies to other software/hardware technologies.



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The BRIDG SCC strives to ensure that semantics harmonized into and represented in one version are still available in the next version. However, as more is learned about any given semantic, the representation may change from one version to the next. The core concept is preserved but may map to a different BRIDG class or attribute. Documentation provided with the model helps users understand where their semantics reside. Each class and attribute in the BRIDG UML model is tagged with the name of the source model element(s) to which it is mapped.